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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/709530
Filing Date	05/12/2004
First Named Inventor	MULLINS, et al.
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	S0002-US03

Total Number of Pages in This Submission: 8

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance communication to Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):

Remarks

Form 1449 (1 page), copies of documents (5 pages)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	John R. Merkling (Reg. No. 31716)
Signature	
Date	12 May 2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Central Fax: 703-872-9306 YH 5/12/04

Typed or printed name	Yanmin Huang		
Signature		Date	5/12/2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Mr. William M. Townsend
Senior Regulatory Specialist
GAMBRO Healthcare
1185 Oak Street
Lakewood, CO 80215-4498

Re: K981085
Gambro® Water Purification System
Dated: March 23, 1998
Received: March 25, 1998
Regulatory Class: II
21 CFR 876.5665/Procode: 78 FIP

Dear Mr. Townsend:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MBRO Healthcare

1185 Oak Street
Lakewood, CO 80215.4498
303.232.6800

March 23, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: **510(k) Notification for Gambro® Systems, Inc. "Gambro® Hemodialysis Water Treatment System"**

Dear Sir or Madam:

This Premarket Notification is being submitted in accordance with Section 510(k) of the Food, Drug and Cosmetics Act and 21 CFR Part 807, to inform FDA that we intend to market a Water Treatment System for Hemodialysis. This Medical Device is being submitted under Section 510(k) of the FD&C Act because we believe that it is substantially equivalent to other Water Purification Systems for Hemodialysis currently in commercial distribution. Evidence of the similarity between our system and others in distribution is contained within this notification. This notification was prepared using the following guidance documents, published by FDA/CDRH/ODE/DRAERD:

- Draft Guidance for the Content of Premarket Notifications (Rev. 3/14/95)
- Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis. (5/30/97)

We consider this notification to be confidential commercial information and ask that you withhold public disclosure of our intent to market the device until such time as you clear it for commercial distribution. Within thirty days of clearance, we will provide a redacted version, as required, for public access through FOI.

If you have any questions regarding this notification, please feel free to contact me by phone (303) 231-4730, or by fax (303) 231-4432.

Sincerely,

William M. Townsend

William M. Townsend
Senior Regulatory Affairs Specialist
Gambro® Healthcare, Inc.